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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,738	05/18/2005	Eric Simard	24913/04004	9696
24/024 7590 03/14/2008 CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114				
EXAMINER				
NATARAJAN, MEERA				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
03/14/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,738

Applicant(s)

SIMARD ET AL.

Examiner

MEERA NATARAJAN

Art Unit

1643

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments filed on 12/21/2007 is acknowledged and entered into the record. Accordingly, Claims 2, 13, and 18-38 have been cancelled without prejudice or disclaimer.
2. Claims 3-12 and 14-17 are pending and will be examined on the merits.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiserodt et al. (US Patent #6277368) in view of Armistead et al. (US Patent #5717092).

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6. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.

7. Hiserodt et al. teaches cellular compositions and methods of using them in cancer immunotherapy, particularly humans. "The [compositions] comprise a source of tumor-associated antigen, and a cytokine-secreting cell line (claim 11, 12, 14, 15). The compositions may be tailored for each type of cancer (claim 7 and 8) or for each subject by mixing tumor antigen with a favorable number of cytokine-producing cells, or with a cocktail of such cells producing a plurality of cytokines at a favorable ratio." (See Abstract of Patent #6277368). The whole-cell tumor compositions taught in Hiserodt et al. have been inactivated by methods known in the art, such as with toxins or irradiation (Column 12, 3rd paragraph) (claim 3-6). Example 7 of Hiserodt et al. discloses a combination method for treatment using IL4-secreting 4CI 107 cells mixed with autologous tumor cells along with adjuvant chemotherapy agents such as Cisplatin, cisplatin/cyclophosphamide, doxorubicin, or taxol (claims 9-10). Hiserodt et al. also disclose the cells or mixture of cells are in a pharmaceutical excipient (ie. carrier) used to treat patients. Hiserodt et al. does not teach all these components (tumor cells, chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Armistead et al.

8. Armistead et al. teach pharmaceutical compositions comprising compounds that can maintain, increase, or restore sensitivity of cells to therapeutic agents. Armistead et al. disclose chemotherapeutic agents in combination with pharmaceutical compounds

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as part of the same composition (see column 19). Armistead et al. disclose that using chemotherapeutic agents in the same composition as pharmaceutical compositions allows one to use a lower dosage of the chemotherapeutic agent than monotherapy (see column 19). A lower dosage range will help prevent multi-drug resistance from occurring.

9. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Hiserodt et al. in the same composition for therapeutic purposes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Armistead et al. in order to avoid multi-drug resistance.

10. Claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Cancer Immunol. Immunother. 1986) in view of Armistead et al. (US Patent #5717092).

11. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.

12. Wang et al. teaches a combination treatment of an anticancer agent, CL 259,763 compound, and an inactivated L1210 leukemia composition given to mice challenged with P388 murine leukemia (claim 3). The mice were vaccinated by IP injection of L1210 leukemia cells that had been irradiated with 4,400 R (Materials and Methods, p. 10) (claim 5 and 6). Wang et al. also discloses "the present study shows that CL

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259,763 has a number of properties characteristic of a biological response modifier" (p.13, Discussion) and therefore teach the limitations of claims 11 and 12. Wang et al. in addition evaluated the effect of CL 259,763 on IL-2 production in tumor-bearing animals and showed that CL259,763 reversed the impairment of IL-2 production in the tumor-bearing mice. These studies meet the limitations of claim 14 and 15, by showing the presence of IL-2. Wang et al. does not teach all these components (tumor cells, chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Armistead et al.

13. Armistead et al. teach pharmaceutical compositions comprising compounds that can maintain, increase, or restore sensitivity of cells to therapeutic agents. Armistead et al. disclose chemotherapeutic agents in combination with pharmaceutical compounds as part of the same composition (see column 19). Armistead et al. disclose that using chemotherapeutic agents in the same composition as pharmaceutical compositions allows one to use a lower dosage of the chemotherapeutic agent than monotherapy (see column 19). A lower dosage range will help prevent multi-drug resistance from occurring.

14. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Wang et al. in the same composition for therapeutic purposes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Armistead et al. in order to avoid multi-drug resistance.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the reply filed 12/21/2007.

Conclusion

15. Claims 3-12 and 14-17 are rejected.
16. No Claim is allowed.
17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643